Board of Directors, pursuant to sections 552b (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of Title 5, United States Code, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Recommendations with respect to the initiation, termination, or conduct of administrative enforcement proceedings (cease-and-desist proceedings, termination-of-insurance proceedings, suspension or removal proceedings, or assessment of civil money penalties) against certain insured banks or officers, directors, employees, agents or other persons participating in the conduct of the affairs thereof:

Names of persons and names and locations of banks authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(6), (c)(8), and (c)(9)(A)(ii) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(6), (c)(8), and (c)(9)(A)(ii)).

Note.—Some matters falling within this category may be placed on the discussion agenda without further public notice if it becomes likely that substantive discussion of those matters will occur at the meeting.

Discussion Agenda:

Recommendation regarding the liquidation of a bank's assets acquired by the Corporation in its capacity as receiver, liquidator, or liquidating agent of those assets:

Case No. 46,356-L—
United American Bank in Knoxville, Knoxville, Tennessee
and
United Southern Bank of Nashville, Nashville, Tennessee
and
First Peoples Bank of Washington County, Johnson City, Tennessee
and
City and County Bank of Knox County, Knoxville, Tennessee
and
City and County Bank of Anderson County, Lake City, Tennessee
and
City and County Bank of Roane County, Kingston, Tennessee
and
United American Bank in Hamilton County, Chattanooga, Tennessee
and
City and County Bank of Jefferson County, White Pine, Tennessee

Personnel actions regarding appointments, promotions, administrative pay increases, reassignments, retirements, separations, removals, etc.:

Names of employees authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(2) and (c)(6) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(2) and (c)(6)).

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550—17th Street, NW., Washington, DC.

Requests for further information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 389-4425.

Dated: November 8, 1985.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 85-27187 Filed 11-12-85; 1:26 pm]

BILLING CODE 6714-01-M

3

FEDERAL ELECTION COMMISSION

DATE AND TIME: Tuesday, November 19, 1985, 10:00 a.m.

PLACE: 1325 K Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. 437g.

Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

DATE AND TIME: Thursday, November 21, 1985, 10:00 a.m.

PLACE: 1325 K Street, N.W., Washington, D.C. (Fifth Floor).

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Setting of Dates of Future Meetings
Correction and Approval of Minutes
Draft AO 1985-33: Cardiss Collins, Citizens to Re-Elect Cardiss Collins
Draft AO 1985-34: J. Curtis Herge, Counsel to National Conservative Political Action Committee
Draft AO 1985-35: William K. Cox, Weirton Steel Corp.

Routine Administrative Matters

PERSON TO CONTACT FOR INFORMATION: Mr. Fred Eiland, Information Officer, 202-523-4065.

Marjorie W. Emmons,

Secretary of the Commission.

[FR Doc. 85-27249 Filed 11-12-85; 3:20 pm]

BILLING CODE 6715-01-M

4

FEDERAL TRADE COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 50 FR 46386, November 7, 1985.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10:30 a.m., November 19, 1985.

CHANGES IN THE AGENDA: The Federal Trade Commission has changed the date and time of its previously announced open meeting from Tuesday, November 19, 1985, 10:30 a.m., to Thursday, November 21, 1985, 10:00 a.m.

Emily H. Rock,

Secretary.

[FR Doc. 85-27166 Filed 11-12-85; 1:07 pm]

BILLING CODE 6750-01-M

5

FEDERAL RESERVE SYSTEM

TIME AND DATE: 11:00 a.m., Monday, November 18, 1985.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board: (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: November 8, 1985.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 85-27110 Filed 11-8-85; 4:38 pm]

BILLING CODE 6210-01-M

6

NATIONAL SCIENCE BOARD

DATE AND TIME: November 22, 1985, 8:00-8:30 a.m. Closed Session; 8:30-10:30 a.m. Open Session.

PLACE: National Science Foundation, Washington, DC.

STATUS: Part of this meeting will be closed to the public. Part of the meeting will be open to the public.

MATTERS TO BE CONSIDERED NOVEMBER 22:

Closed Session (8:00-8:30 a.m.):

1. Minutes—September 1985 Meeting
2. Grants, Contracts, and Programs

Open Session (8:30–10:30 a.m.)

* * * * *

Swearing in Ceremony for Dr. Black and Dr. Hosler as NSB Members

* * * * *

3. Minutes—September 1985 Meeting
4. Chairman's Report
5. Directors Report
6. NSF Advisory Council Presentation
7. Other Business

Thomas Ubois,

Executive Officer.

[FR Doc. 85-27160 Filed 11-12-85; 1:07 pm]

BILLING CODE 7555-01-M

7

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of November 11, 18, 25, and December 2, 1985.

PLACE: Commissioners' Conference Room, 1717 H Street, NW., Washington, DC.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Week of November 11

Thursday, November 14

2:00 p.m.
Continuation of 9/11 Discussion of Proposed Station Blackout Rule (Public Meeting)
3:30 p.m.
Affirmation/Discussion and Vote (Public Meeting)
a. Final Amendments to 10 CFR 50.12, "Specific Exemptions" (tentative)
b. Review of ALAB-817 (In the Matter of Commonwealth Edison Company (Braidwood Nuclear Power Station, Units 1 and 2) (tentative)

Friday, November 15

10:00 a.m.
Discussion/Possible Vote on Full Power Operating License for River Bend (Public Meeting)
2:30 p.m.
Briefing on Policy Statement on Nuclear Power Plant Standardization (Public Meeting)

Week of November 18

Tentative

Monday, November 18

10:30 a.m.
Discussion of Management-Organization and Internal personnel Matters (Closed—Ex. 2 & 6)

Tuesday, November 19

11:00 a.m.
Periodic Meeting with Advisory Panel on Decontamination of TMI-2 (Public Meeting)
2:00 p.m.
Briefing by Executive Branch (Closed—Ex. 1)
3:30 p.m.
Discussion of Exemption Requests—Environmental Qualification (Public Meeting)
4:30 p.m.
Affirmation Meeting (Public Meeting) (if needed)

Week of November 25

Tentative

Tuesday, November 26

2:00 p.m.
Discussion of 1986 Policy and Planning Guidance (Public Meeting)
3:30 p.m.
Affirmation Meeting (Public Meeting) (if needed)

Week of December 2

Tentative

Friday, December 6

11:30 a.m.
Affirmation Meeting (Public Meeting) (if needed)

ADDITIONAL INFORMATION: Discussion of Management-Organization and Internal Personnel Matters (Closed—Ex. 2 & 6) was held on November 1.

Discussion of Management-Organization and Internal Personnel Matters (Closed—Ex. 2 & 6) was held on November 5.

Discussion of Management-Organization and Internal Personnel Matters (Closed—Ex. 2 & 6) was held on November 7.

TO VERIFY THE STATUS OF MEETINGS CALL (RECORDING)—(202) 634-1498.

CONTACT PERSON FOR MORE INFORMATION: Julia Corrado (202) 634-1410.

Julia Corrado,

Office of the Secretary.

November 11, 1985.

[FR Doc. 85-27111 Filed 11-8-85; 4:48 pm]

BILLING CODE 7592-01-M

8

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

TIME AND DATE: 10:00 a.m., Thursday, November 21, 1985.

PLACE: Suite 410, 1825 K Street, NW., Washington, DC

STATUS: Because of the subject matter, it is likely that this meeting will be closed.

MATTER TO BE CONSIDERED: Discussion of specific cases in the Commission adjudicative process.

CONTACT PERSON FOR MORE INFORMATION: Mrs. Mary Ann Miller, (202) 634-4015.

DATED: November 12, 1985.

Earl R. Ohman, Jr.,

General Counsel.

[FR Doc. 85-27250 Filed 11-12-85; 3:20 pm]

BILLING CODE 7600-01-M

9

SYNTHETIC FUELS CORPORATION

Meeting of the Board of Directors

ENTITY: United States Synthetic Fuels Corporation.

ACTION: Notice of Meeting.

SUMMARY: Interest members of the public are advised that a meeting of the Board of Directors of the United States synthetic Fuels Corporation will be held at the time, date and place specified below. This public announcement is made pursuant to the open meeting requirements of section 116(f)(1) of the Energy Security Act (94 Stat. 611, 637; 42 U.S.C. 8701, 8712(f)(1)) and section 4 of the Corporation's Statement of Policy on Public Access to Board meetings. During the meeting, the Board of Directors will consider a resolution to close the meeting pursuant to Articel II, section 4 of the Corporation's By-laws, section 116(f) of the said Act and Sections 4 and 5 of the said policy.

Open Session

I. Call to Order—Chairman's Opening Remarks
II. Approval of Board Minutes
III. Status Review of Outstanding Letter of Intent Projects
IV. Consideration of Remaining Third General Solicitation Project—Paraho-Ute
V. Consideration of Project Proposals under the Tar Sands Solicitation
VI. Consideration of Eastern Bituminous Coal Solicitation Proposals
1. Status Report on Proposals Received under Fixed-Bed Slagger Category
2. Consideration of Qualification Proposals in the Fluidized-Bed and Entrained-Flow Categories

Closed Session

VII. Establishment of Milestones for Fourth General Solicitation Projects
VIII. Status Review of Outstanding Letter of Intent Projects
1. Cathedral Bluffs Downscaling Proposal
2. Seep Ridge Documentation Issues
IX. Status Report on Union Project (Loan Guarantee)

TIME AND DATE: 10:30 a.m., November 19, 1985.

PLACE: 2121 K Street, NW, Rooms 503 and 403, Washington, DC 20586.

PERSON TO CONTACT FOR MORE INFORMATION: If you have any questions regarding this meeting, please contact Ms. Karen Hutchison, Director-Media Relations, at (202) 822-6455.

United States Synthetic Fuels Corporation.

March Coleman,

Assistant General Counsel-Corporate and Litigation.

November 12, 1985.

[FR Doc. 85-27270 Filed 11-12-85; 3:46 am]

BILLING CODE 0000-00-M

federal register

Thursday
November 14, 1985

Part II

Environmental Protection Agency

40 CFR Parts 141, 142, and 143
National Primary Drinking Water Regulations; Fluoride; Final Rule and Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[WH-FRL-2913-6(b)]

National Primary Drinking Water Regulations; Fluoride

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action under the Safe Drinking Water Act (42 U.S.C. 300f *et seq.*) promulgates a Recommended Maximum Contaminant Level (RMCL) for flouride in drinking water at 4 mg/L. EPA has concluded that dental fluorosis, which was formerly regarded as an adverse health effect and which was the basis for the interim drinking water standard, is not an adverse *health* effect under the Safe Drinking Water Act, but rather a *cosmetic* effect that would adversely affect public *welfare*. However, crippling skeletal fluorosis is an adverse *health* effect which, though extremely rare in the U.S., has been adequately documented to be associated with consumption of drinking water containing fluoride in the U.S. EPA has determined that an RMCL of 4 mg fluoride per liter will protect against crippling skeletal fluorosis with an adequate margin of safety.

RMCLs are *non-enforceable health goals* which are to be set at levels which would result in no known or anticipated adverse health effects and which allow an adequate margin of safety. EPA proposed an RMCL for fluoride of 4 mg/L on May 14, 1985 (50 FR 20164).

Maximum Contaminant Levels (MCLs) are *enforceable standards* and are to be set as close to the RMCLs as is feasible. National Secondary Drinking Water Regulations are to contain secondary maximum contaminant levels (SMCLS) and are set at levels requisite to protect public welfare effects. An MCL and SMCL are being proposed for fluoride in a separate **Federal Register** notice published today.

EFFECTIVE DATE: This rule is effective December 16, 1985.

ADDRESSES: Supporting documents cited in Section VII will be available for inspection at the address listed elsewhere in today's **Federal Register** in which a National Primary Drinking Water Regulation is proposed and at the Drinking Water Supply Branch Offices in EPA's Regional Offices at the addresses listed below.

I. JFK Federal Bldg., Boston, MA 02203, Phone: (617) 223–6486, Jerome Healy;
II. 26 Federal Plaza, Room 824, New York, NY 10278, Phone: (212) 264–1800, Walter Andrews;
III. 6th & Walnut Sts., Philadelphia, PA 19106, Phone: (215) 597–9873, Bernie Sarnowski;
IV. 345 Courtland Street, Atlanta, GA 30365, Phone: (404) 881–3781, Robert Jourdan;
V. 230 S. Dearborn St., Chicago, IL 60604, Phone: (312) 886–6176; Joseph Harrison;
VI. 1201 Elm St., Dallas, TX 75270, Phone: (214) 767–2620, James Graham;
VII. 726 Minnesota Ave., Kansas City KS 66101, Phone: (913) 236–2815, Gerald R. Foree;
VIII. 1860 Lincoln St., Denver, CO 80295, Phone: (303) 293–1426, Marc Alston;
IX. 215 Fremont St., San Francisco, CA 94105, Phone: (415) 974–8076, Leslie Ragle;
X. 1200 Sixth Ave. V., Seattle, WA 98101, Phone: (206) 442–1225, Jerry Opatz.

Copies of the health criteria and occurrence documents are available for a fee from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161. The toll free number is 800/336–4700; local: 703/487–4650.

The public docket for this final RMCL rule is part of the public docket for the National Primary Drinking Water Regulation proposed elsewhere in today's **Federal Register**. It is available for viewing at the address described in that notice. Comments are not invited on this final rule.

FOR FURTHER INFORMATION CONTACT: Joseph A. Cotruvo, Ph. D., Director, Criteria and Standards Division, Office of Drinking Water (WH–550), Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, telephone (202) 382–7575.

SUPPLEMENTARY INFORMATION:

I. Statutory Requirements

The Safe Drinking Water Act (42 U.S.C. 300f, *et seq.*) ("SDWA" or "the Act") requires the EPA to establish primary drinking water regulations which (1) apply to public water systems; (2) specify contaminants which in the judgment of the Administrator, may have any adverse effect on the health of persons; (3) specify for each contaminant either (a) MCLs or (b) treatment techniques. See Section 1401(1), 42 U.S.C. 300f. A treatment technique requirement would only be set if "it is not economically or technologically feasible" to ascertain the level of a contaminant in drinking water.

The SDWA includes provisions for interim and revised regulations. See Section 1412, 42 U.S.C. 300g–1. Interim regulations were to be established within 180 days of enactment of the SDWA. (See 40 FR 59570, Dec. 24, 1975). Revised regulations are to be developed in two steps: the Agency is to establish RMCLs and then establish MCLs as close to the RMCLs as feasible. MCLs are to be proposed at the time of promulgation of the RMCLs.

RMCLs are non-enforceable health goals. RMCLs are to be set at a level at which, in the Administrator's judgment, "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety". See Section 1412(b)(1)(B).

MCLs are the enforceable standards. MCLs must be set as close to RMCLs as is feasible. Feasible means "with the use of the best technology, treatment techniques and other means, which the Administrator finds are generally available (taking costs into consideration)." See section 1412(b)(3).

RMCLs alone have no legal impact on public water systems or the public. By promulgating RMCLs, no system is forced to remove contaminants to this level or to take other action regarding contaminants. RMCLs only serve as goals for the Agency in the course of setting MCLs and are therefore initial steps in the MCL rulemaking. In some cases, the MCLs will be set very close to the RMCLs; in other cases control processes or economic considerations may dictate an MCL that is not as close. In any case, it is the MCLs that must be met by public water systems. Non-compliance with an RMCL cannot be the basis of an enforcement action under Section 1414 of the Safe Drinking Water Act.

National Secondary Drinking Water Regulations (NSDWR) (section 1412(c)) are also authorized under the SDWA. A National Secondary Drinking Water Regulation is defined in section 1401(2) as "a regulation which applies to public water systems and which specifies the maximum contaminant levels which, in the judgment of the Administrator, are requisite to protect the public welfare." NSDWRs are not Federally enforceable. Secondary Maximum Contaminant Levels (SMCLs) were established in 1979

for 12 parameters (44 FR 42196, July 19, 1979).

States may assume primary enforcement responsibility (primacy) for public water systems under SDWA Section 1413. To assume primacy, States must adopt drinking water regulations that are no less stringent than EPA's National Primary Drinking Water Regulations and other supporting authority. (*See* SDWA section 1413(a)). States must, therefore, adopt EPA's primary MCLs but need not adopt the RMCLs or the Secondary MCLs to assume or retain primacy.

II. Background

In 1975, EPA promulgated the National Interim Primary Drinking Water Regulations under section 1412 of the Safe Drinking Water Act. EPA set an MCL for fluoride which varied from 1.4 mg/L to 2.4 mg/L, depending upon annual average ambient air temperatures. These levels were considered to be twice the optimum level (0.7 to 1.4 mg/L); this "optimum" is considered by some to be a proper balance between the prevention of dental caries and the occurrence of objectionable dental fluorosis (McClure, 1970). Dental fluorosis is a mottling of dental enamel characterized by staining and/or pitting. Objectionable dental fluorosis is the more serious form, which is classified as "moderate" and "severe" and involves visible dark stains and pitting of the teeth. The Agency set this MCL on the basis that higher levels of fluoride in drinking water could produce adverse health effects by increasing the occurrence of objectionable dental fluorosis. This MCL was identical to a previous U.S. Public Health Service Standard that was established in 1962.

As discussed in the May 14, 1985 proposal (50 FR 20164), the State of South Carolina filed a petition on June 4, 1981 which requested that EPA delete fluoride from the Primary Drinking Water Regulations. South Carolina sued EPA in 1984, seeking faster action in EPA's rulemakings on fluoride. *South Carolina Department of Health and Environmental Control* v. *U.S. Environmental Protection Agency, et al.*, No. 3:84–0676–15 (D.S.C. April 4, 1984. On January 18, 1985, EPA and South Carolina signed a Consent Decree that set forth a schedule for rulemaking on EPA's decision whether to regulate fluoride under the Revised Regulations. Today's rule is one step toward implementing that decree.

In developing the proposal, the agency reexamined data used in setting the original MCL for fluoride and evaluated new data. The agency considered (see 50 FR 20164) the following options for the regulation of fluoride:

1. Propose a National Revised Primary Drinking Water Regulation to protect against moderate and severe dental fluorosis and set the RMCL at 1 or 2 mg/L, as appropriate.

2. Propose a National Revised Primary Drinking Water Regulation finding that crippling skeletal fluorosis (but not dental fluorosis) is an adverse health effect and set the RMCL at 4 mg/L; propose a National Secondary Drinking Water Regulation to warn against dental fluorosis (a cosmetic effect), setting a secondary MCL at 2 mg/L.

3. Delete fluoride from the National Primary Drinking Water Regulations based upon a finding that levels of fluoride in U.S. drinking water are not associated with any adverse health effects; propose a Secondary MCL of 2 mg/L to warn against the cosmetic effects of dental fluorosis. Under Option 2 and Option 3, monitoring and public notification would be required.

The Agency proposed Option 2 for the regulation of fluoride. In making this decision, the Agency concluded that "based upon the information available at this time, EPA believes that crippling skeletal fluorosis is an adverse health effect that can be caused by excessive amounts of fluoride in drinking water, and that 4 mg/L is the level below which no known or anticipated adverse effect on health of persons occur and which allows an adequate margin of safety. Thus, an RMCL is proposed at 4 mg/L" (50 FR 20164). The Agency stated that it now believed that objectionable (moderate and severe) dental fluorosis is not an adverse health effect under the Safe Drinking Water Act, but rather a cosmetic effect that would adversely affect public welfare and it should be regulated under the NSDWRs. The Agency, therefore stated that at the time of proposal of the MCL for fluoride, it planned to propose a Secondary MCL at 2 mg/L. The agency also noted that it was considering proposing monitoring and public notification requirements for the NSDWR under sections 1445 and 1450(a)(1) of the SDWA to assure that the users of public water supplies which are likely to contribute to staining and pitting of dental enamel of children will be fully aware of the possible effects and the methods for their prevention.

In addition, the agency proposed to delete the temperature dependency for fluoride because it determined that there were insufficient data to quantitatively predict the role of temperature in drinking water consumption. Thus, the proposed RMCL was not based on a sliding temperature scale.

III. Explanation of Final RMCL and Other Regulations Proposed Today

A. Final RMCL

Based on the information summarized in the Drinking Water Criteria Document on Fluoride (EPA 1985), the May 14, 1985 proposal and all comments on that proposal, the EPA is promulgating the fluoride RMCL at 4 mg/L. The legal and factual basis for this final rule is explained in this section.

The SWDA authorizes EPA to establish RMCLs for "each contaminant which, in [the Administrator's] judgment . . . may have any adverse effect on the health of persons." See section 1412(b)(1)(B). RMCLs are to be set at a level to prevent known or anticipated adverse effects. The question of what adverse effects are associated with fluoride has been a controversial aspect of this rulemaking. In the case of regulating fluoride under the SDWA, the EPA agrees with the Surgeon General that adverse health effects are considered to be death, gastrointestinal hemorrhage or irritation, arthralgias, and crippling fluorosis (Shapiro 1983; Koop 1984) or any other effect which results in functional impairment. The EPA agrees with the Surgeon General, American Medical Association, the American Dental Association, State of South Carolina, the Association of State and Territorial Dental Directors, the Association of State and Territorial Health Officials and the National Institute for Dental Research (NIDR), that the evidence is inadequate to conclude that dental fluorosis is an adverse health effect.

Regarding other dental effects, the EPA agrees with the Surgeon General (Koop 1982) and the *ad hoc* committee headed by the Chief Dental Officer of the U.S. Public Health Service (Albertini *et al.* 1982) that based upon the available scientific data "no sound evidence exists which shows that drinking water with the various concentrations of fluroide found naturally in public water supplies in the U.S. has any adverse effect on dental health as measured by loss of function and tooth mortality." A draft report on an NIDR study provides additional evidence to that effect. Specifically, Eklund *et al.* (1984) observed that while, as expected, there was a high incidence of dental fluorosis resulting from the consumption of water containing fluoride at 4 mg/L, there was no evidence of any clinically significant effects upon the teeth. EPA noted that this study was in progress in the May 14, 1985 proposal and was received as part of the comments. It was also discussed

in the hearings EPA held. This study supports EPA's statement in the preamble of the proposed rule that there is no adequate evidence of chipping, cracking or loss of enamel associated with fluorosis. No evidence of loss of function or injury to the teeth was received in the comments.

There is inadequate evidence to conclude that dental fluorosis leads to psychological and behavioral effects. An independent panel, convened at EPA's request to study the question of psychological and behavioral effects, concluded that persons with dental fluorosis could be at risk of "behavioral problems" as a result of an "impaired self-image" or "loss of self-esteem." In particular, the panel believed that dental fluorosis would effect the perception of physical attractiveness. The panel noted that facially attractive persons are viewed as more self-confident and are thought to be more socially skilled. Persons who are not perceived as physically attractive are believed to avoid social behaviors requiring responsiveness, be less academically successful and be more dissatisfied with their physical appearance. In some cases, the panel believed that this could result in psychological distress or anxiety. In addition to the panel report several persons have informed the Agency that they suffered embarrassment and an impaired self-image from dental fluorosis and that they did not want mottled or pitted teeth.

EPA does not believe that these effects, impaired self-image or loss of self-esteem and resulting "behavioral problem," are significant enough to be termed adverse health effects within the meaning of the SDWA; there is no significant impairment to the functioning of body or mind. This is not to say that psychological and behavioral problems could never be adverse health effects. EPA is only stating that the particular effects identified by the panel and commenters are believed not to be adverse health effects. However, these effects may be considered adverse effects on public welfare.

In any event, in EPA's view there is not sufficient supporting scientific evidence that dental fluorosis does lead to any psychological or behavioral effects. The panel recognized that its conclusions were based upon extrapolations from research on the effects of physical characteristics other than dental fluorosis; the panel therefore recommended that research be conducted to directly assess the social, emotional, and behavioral effects of fluoride induced cosmetic effects.

EPA is setting RMCLs for contaminants which may have adverse health effects and which occur or are likely to occur in drinking water. Fluoride at high levels in drinking water can cause crippling skeletal fluorosis—an adverse health effect—and fluoride is present in a significant number of public water systems naturally and by addition. It is present at levels greater than 4 mg/l in a large number of those systems from natural causes. Therefore, EPA is promulgating an RMCL and is proposing elsewhere in today's **Federal Register** a National Revised Primary Drinking Water Regulation for fluoride.

EPA has concluded that a National Primary Drinking Water Regulation is needed to protect against crippling skeletal fluorosis. Specifically, the EPA agrees with the Surgeon General that crippling skeletal fluorosis is an adverse health effect which results from intakes of fluoride of 20 mg/day over periods of 20 years or more (Shapiro 1983; Koop 1984) and concludes that a fluoride drinking water concentration of 10 mg/L, given a 2 L per day drinking water consumption rate, would correspond to this value. EPA notes that crippling skeletal fluorosis, rheumatic attack, pain and stiffness have been observed in a large number of individuals in other countries chronically exposed to fluoride in drinking water at levels of 10 mg/L to 40 mg/L. EPA believes that the two cases of crippling skeletal fluorosis observed in the U.S. (Goldman *et al.* 1971; Sauerbrunn *et al.* 1965) related to the consumption of drinking water, provide additional justification that an RMCL is needed to protect against crippling skeletal fluorosis.

EPA has concluded that an RMCL of 4 mg/L which includes a safety factor of less than 10 (10 is normally used with human data) will provide protection against crippling skeletal flurosis with "an adequate margin of safety." This is in agreement with the conclusion of an expert panel convened for the Surgeon General (Shapiro 1983).

Although EPA has guidelines for selecting safety factors, each issue is considered on a case-by-case basis. Typically the smaller the uncertainty concerning the health data, the smaller the safety factor needed. In the case of fluoride, EPA believes that the uncertainty concerning the levels at which fluoride may present risks is relatively small, thus justifying a smaller safety factor than would be used in cases where the uncertainty is greater.

The Agency has concluded that the RMCL need not be reduced below 4 mg/L because of the two cases of crippling skeletal fluorosis observed in the U.S.

All available evidence leads EPA to the conclusion that the incidence of crippling skeletal fluorosis in the U.S. associated with drinking water is extremely small: only two cases of crippling skeletal fluorosis have been reported in the U.S. over the decades that scientists have examined the effects of fluoride upon bone (Hodges *et al.* 1941; Leone *et al.* 1954, 1955, 1960; Dinman *et al.* 1976; Stevenson and Watson 1957; all as discussed in EPA 1985). In both cases, the persons had both higher levels of water intake and, possibly, significant levels of fluoride from the diet in that both drank large quantities of tea daily. As noted in the next section, tea contains more fluoride than many other foods. In one case, the fluoride level in the water consumed was higher than the final RMCL. The fact that only two cases of crippling skeletal fluorosis have been observed in the U.S. associated with the consumption of drinking water provides convincing evidence that the population at risk at 4 mg/L is negligible.

The proposal and public comment also addressed cancer and other effects that have been reportedly linked to fluoride. EPA agrees with the Working Party on the Fluoridation of Water and Cancer (the Knox Report) which was charged by the Government of Great Britain "to reappraise the published and otherwise available data and conclusions on cancer incidence and mortality amongst populations whose drinking water is either artifically fluoridated or contains high levels of fluoride from natural sources" (Knox 1985). The Knox Report found "nothing in any of the major classes of epidemiological evidence which could lead us to conclude that either fluoride occurring naturally in water, or fluoride added to water supplies, is capable of inducing cancer, or of increasing the mortality from cancer. This statement applies both to cancer as a whole, and to cancer at a large number of specific sites."

With the exception of crippling skeletal fluorosis, EPA also agrees with the Surgeon General (Koop 1982) and the *ad hoc* committee headed by the Chief Dental Officer of the U.S. Public Health Service (Albertini *et al.* 1982) that "no sound evidence exists which shows that drinking with the various concentrations of fluoride found naturally in public water supplies in the U.S. has an adverse effect on general health." The Agency has come to this conclusion after careful consideration of health evidence of carcinogenicity, allergic reactions, and the other alleged health effects of fluoride. Some of these

effects occur at much higher levels than that of the RMCLs; other effects are not believed to be associated with fluoride. The EPA Drinking Water Criteria Document on Fluoride (EPA 1985) and the Comments and Response Document discuss these findings at some length. In addition, EPA agrees with the Surgeon General that "4 times optimum in the U.S. drinking water supplies is a level that would provide no known or anticipated adverse health effect with a margin of safety" (Shapiro 1983; Koop 1984) and has therefore set the RMCL at 4 mg/L.

B. Other Regulations Proposed Today

Elsewhere in today's **Federal Register**, EPA is proposing regulations which flow directly from the final RMCL. In a separate notice, EPA is proposing a National Secondary Drinking Water Regulation for fluoride based on dental fluorosis. EPA is proposing an SMCL at 2 mg/L based on a balance of the beneficial effects fo fluoride and the occurrence of moderate to severe dental fluorosis, an adverse effect on public welfare. This action is consistent with the Surgeon General and the conclusions of an *ad hoc* committee headed by the Chief Dental Officer of the U.S. Public Health Service who concluded the following, respectively:

- I encourage communities having water supplies with fluoride concentrations of over two times optimum to provide children up to age nine with water of optimum fluoride concentration to minimize the risk of their developing objectionable dental fluorosis (Koop 1982).
- "That two times the optimum concentration" approximately 2 mg/L—"be used as a guide as to which communities should consider fluoride removal, since there is evidence that dental health benefits do not significantly improve above that point (Albertini *et al.* 1982 as quoted in Shapiro 1983).

In the same notice, EPA is also proposing Interim and National Revised Primary Drinking Water Regulations with MCLs of 4 mg/L based on best technology generally available (considering cost). Also proposed are monitoring, reporting, and recordkeeping requirements. The basis of these and other regulations is explained in detail in the separate notice.

IV. Human Exposure

The May 14, 1985, **Federal Register** notice summarized the available information on the occurrence of fluoride in drinking water, population exposure estimates and toxicology data. Detailed information was presented in the Criteria and Occurrence Documents. The following information is intended to very briefly summarize these documents which should be consulted for details.

A. Human Exposure to Fluoride

Virtually all foods contain trace amounts of fluoride—see Table 1. The health effects associated with fluoride and the doses at which they occur, are based upon epidemiology studies which necessarily incorporate dietary exposures to fluoride. Thus, while food can be a significant source of fluoride in unusual cases, the Agency believes that it is unnecessary to adjust the RMCL because of dietary exposure.

Adequate data are available to estimate the daily intake of fluoride both exclusive of water—see Table 2—and due to the consumption of water—see Table 3.

TABLE 1.—FLUORIDE CONTENT OF VARIOUS FOODS

Food	Fluoride content (ppm)	
	WHO (1970)	NAS (1980)
Meats	0.2 to 2.0	0.01 to 7.7.
Offal	2.3 to 10.1	(1)
Fish	5.8 to 25.9	<0.10 to 24.
Shellfish	0.7 to 2.0	(1)
Eggs	1.2	0.00 to 2.05.
Milk	0.07 to 0.22	0.04 to 0.55.
Cheese	1.62	0.13 to 1.62.
Butter	(1)	0.4
Tea (average, dry weight).	97.0	(1)
Coffee	0.2 to 1.6	0.2 to 1.6.
Citrus fruits	0.03 to 0.36	0.04 to 0.36.
Noncitrus fruits	0.11 to 1.32	0.02 to 1.32.
Cereals and cereal products.	0.1 to 0.7	0.10 to 20.
Vegetables and tubers	0.1 to 1.0	0.10 to 3.0.
Beer and wine	0.07 to 0.24	0.0 to 6.34.
Sugar	(1)	0.10 to 0.32.

[1] No data provided.

TABLE 2.—REPORTED DAILY INTAKE OF FLUORIDE

[Exclusive of Water]

Source	Category of individual	Daily intake (mg/kg)
WHO (1970)	Age 1 to 3	0.0024 to 0.024.
	4 to 6	0.002 to 0.020.
	7 to 9	0.0019 to 0.019.
	10 to 12	0.0016 to 0.016.
NAS (1980)	Adult	0.0028 to 0.0043.
Underwood (1973)	Adult	0.0043 to 0.0071.
Hodge and Smith (1970).	Adult	0.0043 to 0.011.
Singer et al. (1980) [1].	Young adult male	0.0043 to 0.0086.

[1] Excludes all beverages.

TABLE 3.—ESTIMATED INTAKE OF FLUORIDE RELATIVE TO DRINKING WATER

Source	Daily dose (mg/kg)		
	Infant [a]	Child [b]	Adult [c]
Drinking water consumption (1 mg/L)	[d]	0.051	0.034
Air (0.05 μg/m³)	0.00002	0.00002	0.00002
Food (from Table 5)	0.24	0.002 to 0.02	0.0043 to 0.011

[a] The infant is assumed to weigh 3.5 kg, consume solely 0.85 L of formula reconstituted with tap water, and inhale 3.4 m³ a day.
[b] The child is assumed to weigh 33 kg, drink 1.4 L of tap water, and inhale 15 m³ a day.
[c] The adult is assumed to weigh 70 kg, drink 2 L of tap water, and inhale 23 m³ a day.
[d] No value is listed since the infant's intake of water is by formula and is counted as food.

B. Temperature and Fluoride Intake

The present MCL for fluoride establishes the allowable concentration as a function of the average maximum daily temperature. The MCL ranges from 1.4 mg/L for public water systems serving populations located where the annual average maximum temperature is above 79.3 °F to 2.4 mg/L for systems serving populations located where temperatures are below 53.7 °F. However, EPA has concluded that the available data are insufficient to quantitatively incorporate temperature in drinking water regulations. This conclusion and its bases are explained in more detail in the next section and the Comment and Response document.

V. Summary of Comments and Responses

EPA received over 400 written public comments on the May 14, 1985, proposal. EPA also held two full days of public hearings in Washington, DC. The principal issue was whether fluoride in drinking water posed adverse health effects. Many of the comments from citizens and citizen's groups stated that the RMCL should be set at 2 mg/L or lower because of the many adverse health effects alleged to be associated with fluoride. Many States and organizations of health professionals believed that fluoride in drinking water causes no adverse health effects. The comments addressed a wide range of other issues relating to the RMCL. The major comments are summarized below in the following manner:

A. Public comments on the three major options EPA considered for the regulation of fluoride and comments on questions EPA raised in the May 14, 1985 proposal directly related to these options.

B. Public comments on certain questions EPA raised in the May 14,

1985 proposal not addressed in A. above or elsewhere.

C. Other public comments; comments that there were other adverse health effects, e.g., oncogenicity, mutagenicity.

A more detailed summary of the comments and EPA's response to these comments as well as a review of the scientific papers submitted are provided in the background document, "Summary of Comments and Responses from the May 14, 1985, Fluoride RMCL Proposal."

A. Public Comments to Options EPA Considered and Related Questions

The following is a summary of the public comments and the EPA response to those comments dealing with the three options EPA considered. In this section, we also address those questions we raised relating to these options.

Option 1

Propose a Primary Drinking Water Regulation based upon protection from moderate and severe dental fluorosis and set the RMCL at 1 or 2 mg/L, as appropriate.

Comments. Relatively few comments specifically addressed this option in any detail or provided relevant data.

Those that specifically favored Option 1 merely stated their view that dental fluorosis was an adverse health effect and an RMCL of 1 or 2 mg/L was necessary to prevent dental fluorosis.

Those opposed to Option 1 may be divided into two categories. First, some commenters believed that no adverse health effects are associated with the consumption of fluoride in U.S. drinking water and thus Option 2 or 3 would be appropriate. These commenters did not believe that dental fluorosis itself was an adverse health effect. In this connection, a Draft National Institute of Dental Health (NIDR) study (Eklund *et al.* 1984) concerning dental fluorosis—noted as in progress in the May 14, 1985 proposal—was submitted. Various dental parameters of the citizens of Lordsburg and Deming, New Mexico were compared. Lordsburg and Deming are very similar except that the fluoride content of Lordsburg drinking water—approximately 4 mg/L—is considerably higher than the 0.7 mg/L found in Deming.

In the Eklund *et al.* (1984) study, the authors concluded that the consumption of drinking water containing 4 mg/L or less does not result in any adverse effect upon the teeth—e.g. periodontal disease—and that the consumption of drinking water containing 4 mg/L, as compared to 0.7 mg/L, results in an increase in the level of dental attrition (wearing away of the teeth) "which does not appear to be of any clinical importance."

Second, another group of commenters opposed to option 1 believed that other serious adverse health effects—e.g. oncogenicity, mutagenicity—are associated with the consumption of fluoride in U.S. drinking water and thus an RMCL less than 1 or 2 mg/L would be appropriate. A large number of studies were submitted concerning the possible health hazards that fluoride may present (many of these had already been reviewed by EPA). These studies have been grouped by effect—e.g. oncogenicity, mutagenicity—and discussed in Section C.

The Agency specifically requested comments on whether moderate and severe dental fluorosis should be considered adverse health effects or whether they should be considered cosmetic and aesthetic effects. EPA asked whether dental fluorosis should be considered an indicator of excess dosages of fluoride which may potentially result in other adverse effects, such as crippling skeletal fluorosis, at sufficient dosages and duration of exposure.

The following comments were received on these questions.

(1) Based on the conclusions of the National Drinking Water Advisory Council (NDWAC), the World Health Organization (WHO) and others, dental fluorosis is an adverse health effect: EPA should have followed the advice of the NDWAC; (2) Based on the information presented in the May 14, 1985 proposal, dental fluorosis is not an adverse health effect; and (3) While a number of comments stated that dental fluorosis was a sensitive or was the most sensitive indicator of fluoride toxicity, EPA received no relevant information on whether dental fluorosis in an individual progresses beyond cosmetic effects to adverse health effects.

The Agency also asked whether moderate and severe fluorosis should be deemed adverse health effects because of potential psychological and behavioral effects. Several commenters—one based on personal experience—stated that the potential psychological and behavioral effects of moderate and severe dental fluorosis were, in their opinion, adverse health effects. Several other commenters stated their opinion that the psychological and behavioral effects that might arise from dental fluorosis are not adverse health effects *per se*.

EPA Response. Based on the Drinking Water Criteria Document of Florida (EPA 1985), the May 14, 1985 proposal and all public comments, the EPA has reached the following conclusions.

The Eklund *et al.* study (1984) provides objective evidence that dental fluorosis associated with fluoride levels up to and including 4 mg/L does not have an adverse effect upon dental health. This finding is in agreement with the *ad hoc* committee headed by the Chief Dental Officer of the U.S. Public Health Service (Albertini *et al.* 1982). EPA agrees with the commenters that stated that dental fluorosis is not an adverse health effect in the context of the Safe Drinking Water Act; EPA believes that adverse health effects, at least for fluoride, should be measured by functional impairment.

EPA does not believe that there is adequate evidence to conclude that moderate and severe dental fluorosis lead to psychological and behavioral effects. In any case, the psychological and behavioral effects that are speculated to be caused by fluoride (impaired self-image) are not known to result in function impairment.

There is no evidence to support the position that dental fluorosis progresses in an individual beyond cosmetic effects to any adverse health effects. EPA was not aware of any at the time of proposal and no new evidence on this issue was received.

The Safe Drinking Water Act requires the Administrator to set the RMCL at a level which "in his judgment" results in no adverse health effect. Therefore, the Act calls on the Administrator to reach his own conclusions in reviewing the health evidence and views of others on adverse health effects. While EPA considered the advice of the NDWAC and all other organizations, this advice was weighed together with all other relevant information in reaching a decision.

In that no adequate evidence to the contrary was received, the EPA reaffirms its conclusion, presented in the proposal, that dental fluorosis is not an adverse health effect under the SDWA. EPA is supported in this decision by the Surgeon General (Koop 1982), and the Chief Dental Officer of the U.S. Public Health Service (Albertini *et al.* 1982); support for this conclusion was also provided by the American Medical Association, the American Dental Association, State of South Carolina, the Association of State and Territorial Dental Directors, the Association of State and Territorial Health Officials, and the National Institute for Dental Research. (NDWAC 1982).

Option 2

Propose a Primary Drinking Water Regulation based upon a determination that crippling skeletal fluorosis but not dental fluorosis is an adverse health effect and set the RMCL at 4 mg/L. Propose a Secondary Drinking Water Regulation to protect against cosmetic effects of dental fluorosis and set the secondary MCL at 2 mg/L.

Comments. Those comments in favor of this option stated that dental fluorosis was not an adverse health effect and that an RMCL of 4 mg/L would protect against crippling skeletal fluorosis "with an adequate margin of safety".

Most of the comments opposed to this option can be divided into the following categories.

- Those who, based on the information presented in the May 14, 1985 proposal, concluded that the fluoride levels found in U.S. drinking water are not associated with an adverse health effect and thus there is no need for NPDWR.
- Those who concluded that, because the fluoride levels found in U.S. drinking water are associated with crippling skeletal fluorosis and/or other adverse health effects—e.g. oncogenicity, mutagenicity, a fluoride RMCL of 4 mg/L provides an inadequate Margin of Safety.
- Those who concluded that the toxicity of fluoride is insufficiently characterized and thus the Agency should wait until the toxicity of fluoride is completely understood or alternatively wait until the results of the ongoing NCI rat and mouse bioassay are available before setting a fluoride RMCL.

In addition, there were a few comments concerned with the suggested secondary standard. Those in favor, implicitly, stated that the secondary standard was reasonable while those opposed stated that it was either too costly or should be left to the discretion of the States.

In the proposal, the Agency noted that it believed that crippling fluorosis is an adverse health effect which occurs at intakes of approximately 20 mg/day for 20 years. EPA requested comment on the data supporting this position and the safety factor the Agency has employed.

Commenters pointed out that crippling skeletal fluorosis *has* been observed in the U.S. associated with the consumption of drinking water (Goldman *el al.* 1971; Sauerbrunn *el al.* 1965). These cases had not been identified by EPA prior to proposal. Specifically, crippling skeletal fluorosis was noted in both a 55 year old male (Goldman *el al.* 1971) and a 64 year old male (Sauerbrunn *el al.* 1965), who drank large but unknown quantities of drinking water over a period of 20 or more years. The amount of water consumed is estimated by the EPA to be 6 L per day containing, respectively, somewhere between 2.4 and 3.5 mg fluoride/L in one case and between 4.0 and 7.8 mg/L in the other. In addition, both individuals consumed large quantities of tea daily (amount unspecified) which also contributed to their fluoride intake.

Some commenters believed that no adverse health effects associated with the consumption of fluoride in drinking water had been observed in the U.S. (they were presumably not aware of this data).

Several commenters argued that a larger safety factor should be used by the EPA in determining the RMCL.

EPA Response. Based on its review of the evidence as presented in the Drinking Water Criteria Document on Fluoride (EPA 1985), the May 14, 1985 proposal and all public comments, the EPA has reached the following conclusions.

Crippling skeletal fluorosis is an adverse health effect which can occur from high levels of fluoride in drinking water. Therefore, the EPA agrees with the Surgeon General as explained in Section III (Shapiro 1983; Koop 1984). With the exception of two cases of crippling skeletal fluorosis identified in the U.S., crippling skeletal fluorosis, rheumatic attack, pain and stiffness have not been observed in the U.S. However, these effects have been observed in a large number of individuals in other countries chronically exposed to fluoride in drinking water at levels of 10 mg/L to 40 mg/L.

Crippling skeletal fluorosis has been observed in the U.S. resulting in part from the consumption of large volumes of high fluoride water (est. 6 L/day) over a long period of time (Goldman *el al.* 1971; Sauerbrunn *el al.* 1965). In one report, no figures were given, but the examining physicians concluded that the patient had "a lifetime history of drinking large quantities of water" (Goldman, *el al.*). In the other report, the patient's fluid intake and output was 4 to 10 liters/24 hour period; four years later a 7 to 8 liter water exchange was measured (Sauerbrum, *el al.*) He was also reported to have " 'always' drank excessively large quantities of water." The Agency believes that an estimate of 6 liters per day intake is reasonable (and conservative). As noted below, 6 liters/day would be unusually high, given that average water consumption is somewhat less than 2 liters/day and over 99.9% of the population is believed to consume 5.5 liters or less.

It is acknowledged that these persons also probably received more fluoride than most persons from their diet due to the consumption of quantities of tea (which contains more fluoride than other foods). Because only two cases of crippling skeletal fluorosis have been observed over the decades this subject has been investigated, EPA has concluded that the possibility of crippling skeletal fluorosis associated with drinking water in the U.S. is extremely low. Based on this evidence, EPA concludes that crippling skeletal fluorosis has been detected in the U.S.

EPA agrees with the Knox Report that there is no evidence that fluoride, whether natural or artificially "added to water supplies, is capable of inducing cancer, or of increasing the mortality from cancer" (Knox 1985); other than crippling skeletal fluorosis, EPA can find no evidence adequate to conclude that exposure to fluoride in U.S. drinking water is associated with other adverse health effects—e.g. oncogenicity, mutagenicity (See Section C below). While it is always desirable to have additional information, the Agency believes that adequate information is at hand to set a fluoride RMCL. The EPA is aware that there is an ongoing chronic rat and mouse bioassay designed to measure the oncogenic potential of fluoride. EPA will examine the results of this bioassay when it becomes available to determine whether there is any basis for reconsideration of the RMCL.

EPA believes that an RMCL of 4 mg/L will protect adequately against an effect which may occur at a daily ingestion of 10 mg/L (more than 20 mg/day for 20 years) of fluoride (the margin between 10 and 4 mg/L is the margin of safety). Based on SDWA legislative history, EPA believes that an RMCL must protect the U.S. population and those more susceptible to adverse health effects. Based on the calculations of the National Academy of Sciences (NAS 1977), a Canadian Study (EHD 1982) and EPA's own data base, the majority of the population consumes 2 liters of drinking water each day, some of it through preparation of food, consumer prepared beverages, etc. Some persons consume more drinking water and are therefore more susceptible. However, only an extreme few consume amounts as high as 6 L/day as EPA estimates the two individuals did who were afflicted with crippling fluorosis. Over 95% of the population are believed to consume 4 liters per day or less; over 99% of the population are believed to consume 5.5 liters or less (EHD 1982, Price 1985). In

addition, these persons may have consumed more fluoride than an average person because of the consumption of large quantities of tea, or other practices. One of the two consumed water above the RMCL.

EPA believes that an RMCL of 4 mg/L will adequately protect persons who have high water consumption. The Agency believes that the margin of safety is adequate for these persons based on the lack of detection of crippling fluorosis in any significant portion of the population. Some commenters argued that there may be some persons who, through their own dietary practices consume enough fluoride, even when drinking water levels are at 4 mg/L, to develop crippling fluorosis. EPA does not believe that the SDWA requires protection by national regulation of persons who, through unusual practices, may put themselves at risk.

In addition, EPA has concluded that a safety factor less than 10 will provide protection against crippling skeletal fluorosis with an adequate margin of safety. The Agency notes that there are other examples from the Interim Regulations where safety factors smaller than 10 were used to set a drinking water MCL; e.g., nitrate, lead, and barium.

Option 3

Delete fluoride from the Primary Drinking Water Regulations based upon a finding that levels of fluoride in U.S. drinking water are not associated with any adverse health effects. Propose a Secondary MCL of 2 mg/L protect against the cosmetic effects of dental fluorosis.

Comments. While only a few comments specifically addressed this option, it is clear that the majority of the comments were opposed to this option arguing that the fluoride levels found in U.S. drinking water are associated with crippling skeletal fluorosis and other adverse health effects—e.g. oncogenicity, mutagenicity—and thus a fluoride RMCL is clearly necessary.

Those in favor of this option argued that since the levels of fluoride found in U.S. drinking water do not result in crippling skeletal fluorosis or any other adverse health effect, there is no need for NPDWR. Many also argued that the economic cost of an RMCL is not warranted. In addition, the suggested secondary standard was attacked because it was seen as either too costly or it was a matter best left to State discretion.

EPA Response. Because crippling skeletal fluorosis is an adverse health effect that can be caused by consumption of fluoride in drinking water, fluoride is found at significant levels in a large number of public water systems, and cases of crippling fluorosis have been observed in the U.S., EPA must set an RMCL and NPDWR under the Act. EPA is also proposing a secondary MCL of 2 mg/L based on a balance of the beneficial effects of fluoride and the occurrence of moderate to severe dental fluorosis, an adverse effect on public welfare, in agreement with the Surgeon General and the conclusions of an *ad hoc* committee headed by the Chief Dental Officer of the U.S. Public Health Service (Koop 1982; Albertini 1982; Shapiro 1983).

Under the Safe Drinking Water Act, cost of compliance with an RMCL is not a valid consideration in determining whether there are adverse health effects that justify regulation under a NPDWR. Compliance costs are relevant in determining the MCL, as proposed elsewhere in today's **Federal Register**.

B. Public Comments on EPA Questions

The Agency raised a number of questions in the May 14, 1985 proposal. Several of these questions have been discussed earlier in this document while others are discussed in the separate **Federal Register** notice published today which proposes an MCL. The following is the only question directly related to the RMCL not previously addressed in detail or considered elsewhere.

Use of a Single Standard for Fluoride

The proposed RMCL for fluoride, unlike the previous MCL, is a single standard independent of temperature. The Agency sought comments on its proposal not to make the fluoride standard temperature dependent.

Comments. The Agency received comments on its proposal to issue a single standard from the National Institute of Dental Research, the State of Arizona, and the Natural Resources Defense Council. In general, these commenters stated that they were in favor of retaining a consideration of temperature in the RMCL. The commenters, citing no new data, stated that the previously available evidence for such a dependency was considerable and that the Agency had not presented sufficient information to justify abandoning the consideration of temperature. In particular, they stated that the Canadian survey of tap water consumption was not a sufficient basis for going to a single standard.

EPA Response. The Agency has concluded that, while tap water consumption may be affected by climate to a limited degree, the available evidence indicates that the effect does not warrant adjustment of national drinking water standards. This conclusion is based on more recent and more extensive drinking water information and a reanalysis of the technical basis of the current standard.

The current temperature-dependent standard is based on one study Galagan *et al.* (1957) in which the authors studied consumption of tap water of children over a one year period in a temperate city (near Sacramento, CA). The authors did not attempt to survey any other areas of the country or areas where the temperature reaches lower that 50°.

Since the temperature dependent standard was proposed in the early 1960's, EPA reanalyzed the basis for temperature dependency on which the Interim Standard is based and surveys in Canada and the U.S. (EHD 1982, EPA 1984a, Price 1985) have become available.

The Canadian survey was limited in its ability to detect temperature dependent variations in tap water consumption since the summer temperatures of the locations surveyed averaged only 70 °F. However, the survey reported that, for the Canadian population as a whole, there was little or no seasonal or regional variation in drinking water consumption. The survey also indicated that there was no seasonal variation in water consumption for children.

The Agency received several comments stating that the Canadian survey was not sufficient to justify dropping the current temperature dependency. They argued that the study was limited to late summer/fall and that significant changes in consumption would not be expected during these periods. They also argued that the annual average temperature in Canada was colder than in the U.S. and should not be applied in this country. They noted that the report merely speculated as to the reasons for lack of temperature dependency and did not identify the exact reasons with confidence. Commenters noted that 1984 and 1985 documents of EPA on fluoridation based their advice on the temperature dependent standard. The Agency disagrees and believes that the Canadian study demonstrates that tap water consumption does not vary with temperature for temperatures below 70 °F for both adults and children. This finding alone is sufficient to show that the effect of temperature on tap water consumption is non-linear for temperatures below 70 °F and indicates that the temperature relationship used in

the current standard will not accurately predict tap water consumption for cooler areas of the country. These data also suggest that water consumption may not be temperature dependent for areas with temperatures above 70 °; therefore, the Canadian study, based on data from a wide variety of areas, directly contradicts the Galagan study for areas with tempertures below 70 °; because the Galagan study and the Canadian study overlap in temperatures studied, the results of the entire study are called into question.

The Canadian survey examined both warm periods and cold periods and found that consumption did not change significantly between the two. The study hypothesized reasons for the findings but these hypotheses (and their validity) do not affect the findings. Other EPA documents (not part of this rulemaking) referring to fluoridation are based on the existing MCL or to advise systems following engineering practices if they wish to fluoridate using a temperature-dependent approach.

In response to comments, EPA analyzed other data on U.S. populations and concluded that variations in temperature do not appear to significantly affect tap water consumption for the U.S. population as a whole (Price 1985, EPA 1984a, Walker *et al.* 1963). This data was gathered in 1977–78 for the U.S. Department of Agriculture from around the U.S. over a one year period, selected to be statistically representative of the population as a whole. These data and conclusions are consistent with the Canadian study in that no significant temperature effects were found. The seasonal variation for all ages (winter verses summer) was reported to be 6%, see Table 4. The survey also reported variations for four regions of the country, Table 5. Regional variations are less than 15% and do not appear to be a direct function of variations in temperature, i.e., the southern, western, and mid-western regions consume similar levels of tap water.

TABLE 4.—SEASONAL VARIATION OF AVERAGE TAP WATER CONSUMPTION, FOR ALL AGES (L/DAY)

Season	Drinking water consumption
Winter	1.94
Spring	[1] 1.97
Summer	2.07
Fall	[1] 1.95

[1] Not statistically different from winter.

TABLE 5.—REGIONAL VARIATION OF AVERAGE TAP WATER CONSUMPTIONS, FOR ALL AGES (L/DAY)

Region	Drinking water consumption
North East	1.75
Mid-west	[1] 2.0
West	[1] 2.05
South	[1] 2.09

[1] Not statistically different from mid-west. (Price 1985)

Although children were included in the survey, it did not report separate seasonal and regional variations in tap water consumption of children under the age of nine. The Agency concludes it unlikely that there would be a significant variation in the consumption of tap water in children given the lack of variation in the population as a whole.

Further evidence for a small seasonal variation in the consumption of tap water among children is shown by the lack of a seasonal variation among individuals with high consumptions of tap water, see Table 6. As reported by Galagan *et al.* (1957), children have higher levels of tap water consumption than adults on a weight basis. If children's consumption of tap water had a greater seasonal variation than the population as a whole, then the upper tail of the national distribution should display a higher seasonal variation. As shown in Table 6 no such variation is discernable at higher levels of consumption.

Finally, this conclusion is supported by a limited survey of regional variation in tap water consumption (Walker *et al.* 1963). This survey found little or no regional variation in childrens tap water consumption.

TABLE 6.—SEASONAL VARIATION OF THE DISTRIBUTION OF TAP WATER CONSUMPTION IN THE U.S. POPULATION

Consumption (ml/kg)[1]	Season	
	Summer	Winter [2]
0 to 10	0	0
11 to 20	2	3
21 to 30	21	23
31 to 40	32	33
41 to 50	19	19
51 to 60	10	9
61 to 70	6	5
71 to 80	3	2
81 to 90	2	2
91 to 100	1	1
101 to 150	1	1
151 to 200	2	1
Over 200	0	0

[1] Fluid consumption in this Table can not be readily converted to ml/day by the multiplication of a single body weight. Individuals in this study and in the general population exhibit increasing tap water intakes (on a ml/kg basis) with decreasing body weights. Therefore, use of an average weight will result in an overestimate of consumption for the upper end of this distribution.

[2] Consumption of tap water during the fall and spring did not statistically differ from winter consumption.

In addition to the more recent survey information, the Agency has reevaluated the technical basis of the current standard. The current optimal standard is based on two papers, a study by Galagan *et al.* (1957) and a policy paper by Galagan and Vermillion (1957). The basis for a temperature-dependent standard is not a survey of regional or national variation of tap water consumption but a survey of seasonal variation at a single metropolitan location. Galagan *et al.* investigated the variation of tap water consumption for a one-year period as a function of weekly average temperatures for two neighboring communities in California. The survey reported that the average tap water consumption of a group was a linear function of temperature for the temperature range of 50 to 90° F (summer and winter temperatures of that location) and that tap water consumption was approximately 50% higher in summer than winter. The authors stated that the observed relationship between temperature and tap water consumption should be limited to temperature between 50°F and 90°F and may not be valid for areas with different humidities.

The second paper (Galagan and Vermillion 1957) proposed the use of the temperature-tap water relationship as a basis for the modification of the level of fluoride which was considered to be optimum for fluoridating water supplies. They also suggested that further tap water consumption surveys may be necessary. The optimum level of fluoride in drinking water was defined as 1 mg/L for communities in the Chicago area.

The Agency questions establishing a national standard on a relationship from data taken from a single location with a limited population. The temperature dependency suggested by Galagan and Vermillion suggest a variation of 70% is appropriate for different areas. The use of a temperature-tap water relationship of this magnitude would be valid only if the relationship could be demonstrated to accurately predict consumption for seasonal periods and for all regions of the country. The Galagan study is not such evidence and EPA would not now set a temperature dependent standard based on this study alone, if it were the only study available.

In addition, to these technical findings, EPA notes that (1) the current temperature-dependent standard is consistent with the finding that consumption will vary by approximately 70%, while the recent data suggest that if a variation in consumption exists, it is on the order of only a few percent; (2) the National Academy of Sciences did

not endorse temperature dependency in their recommendations on fluoride; (3) the WHO, in establishing its recommended standard for fluoride, set a single level of 1.5 mg/L, and (4) EPA has not used a temperature dependent standard for any other contaminant.

EPA has concluded that, for the purposes of the regulation promulgated today, the recently developed evidence on the temperature and regional variations in tap water consumption does not support the need for a temperature dependent national drinking water standard. As noted in the proposal, the Agency reached this conclusion based on a reevaluation of the Galagan studies and the Canadian Survey. EPA affirms this conclusion in this final rule. The additional U.S. data strongly confirms EPA findings.

C. Other Public Comments

The following is a synopsis of the other major issues raised by the commenters and EPA's response. These and other issues are addressed in more detail in the Comment and Response document. EPA received many studies and scientific abstracts with the public comments. Many of these had already been analyzed in the Drinking Water Criteria Document that was made available to support the proposed rule. Only a few persons reviewed the Criteria document to address EPA's review of the studies. Those comments addressing EPA's conclusions and those that contained new studies were carefully reviewed and discussed in the Comment and Response Document and in this preamble.

1. *Increased Fluoride Exposure.* Several comments stated that EPA had failed to adequately take the reported increases in dietary fluoride into account in setting its RMCL. A number of articles were submitted on this subject.

EPA Response. The Agency has reviewed the comments submitted and supporting articles and agrees that for a number of reasons the total intake (other than drinking water) of fluoride of the general population has increased since the 1940s (Leverett 1982). This increase is difficult to quantitatively estimate but is believed to be much less (<1 mg/L) than the dose received from consuming water at the RMCL.

The Agency believes, however, that the general population's increase in fluoride does not result in sufficient additional dosages such that individuals will be under a significantly greater risk of incurring skeletal fluorosis. Further, the Agency believes that the RMCL does not require an adjustment for increases in fluoride because the margin of safety in the proposed RMCL is sufficient to accommodate the reported increases.

2. *Fluoride Oncogenicity.* A significant fraction of those who objected to Options 1, 2 and 3 stated that fluoride was oncogenic. Thirteen papers directly bearing on this issue were received. Eleven of these papers concluded that fluoride was oncogenic (Burk 1981; Burk 1985; Burk and Graham 1984; Bundock *et al.* 1985; Taylor and Taylor 1965; Yiamouyiannis and Burk 1977; Yiamouyiannis 1983a; Yiamouyiannis 1983b; Okayasu *et al.* 1985; Herskowitz and Norton 1963; Graham and Burk 1984) and one paper (Grandjean *et al.* 1985) concluded that it was unlikely that fluoride was oncogenic. In addition, an extensive and critical review on the epidemiological evidence concerning this issue (and addressing most of the above studies) was provided which concluded that there was no evidence that fluoride in drinking water induces cancer or produces an increase in mortality due to cancer (Knox 1985).

EPA Response. Many of the studies provided to EPA in the comment period had already been reviewed and reported in the Drinking Water Criteria Document on Fluoride (EPA 1985). Few commenters addressed EPA's review of the studies that are the basis for EPA's conclusion in the Drinking Water Criteria Document on Fluoride (EPA 1985) that fluoride did not cause or contribute to cancer.

Based on the Drinking Water Criteria Document on Fluoride (EPA 1985) and the information presented in and the public response to the May 14, 1985 proposal, EPA has concluded that there is not adequate information to conclude that fluoride presents a cancer risk to humans. The Report of the Working Party on the Fluoridation of Water and Cancer (Knox 1985) is particularly relevant in that the Working Party was charged by the Government of Great Britain "to reappraise the published and otherwise available data and conclusions on cancer incidence and mortality amongst populations whose drinking water is either artificially fluoridated or contains high levels of fluoride from natural sources." The Working Party concluded:

> We have found nothing in any of the major classes of epidemiological evidence which could lead us to conclude that either fluoride occurring naturally in water, of fluoride added to water supplies, is capable of inducing cancer, or of increasing the mortality from cancer. This statement applies both to cancer as a whole, and to cancer at a large number of specific sites. In this we concur with the great majority of scientific investigators and commentators in this field. The only contrary conclusions are in our view attributable to errors in data, errors in analytical techniques, and errors in scientific logic.

3. *Mutagenicity.* A large number of comments and scientific studies (see *Response*, below, for details) were received concerning the possible mutagenicity of fluoride. While a majority of the commenters concluded that fluoride is mutagenic, the conclusions of the studies conflict. Some studies concluded that fluoride is mutagenic; other studies concluded that fluoride is not mutagenic.

EPA Response. A detailed review of the scientific studies dealt with in this section are presented elsewhere ("Summary of Comments and Responses from the May 14, 1985 RMCL Proposal"). The following is a brief synopsis of the conclusions EPA has reached concerning these studies.

- Fluoride was negative in an Ames test (Martin *et al.* 1979).
- Fluoride was negative in several sister chromatid exchange assays (Ved Brat 1984a, b; Kram *et al.* 1978).
- Fluoride was negative in a Rec assay in bacillis subtilis (Kanematsu *et al.* 1980).
- Fluoride did not produce DNA strand breaks in mice (Skare *et al.* 1985).
- Fluoride was reported to produce an increased rate of chromosomal aberrations in cultured human leukocytes (Jachimczak and Skotarczak 1978).
- Fluoride was reported to produce an increase in the frequency of both morphological transformations and chromosome aberrations in cultured Syrian hamster cells (Tsutsui *et al.* 1984b).
- Fluoride, in a study with serious deficiencies, was reported to produce an antimutagenic effect in human leukocytes when given in combination with Trenimon, a known mutagen (Slacik-Erben and Obe 1976).
- Fluoride was antimutagenic in *Drosophila* (Vogel 1973); however, others (MacDonald and Luker 1980) have concluded that this antimutagenic effect is an artifact.
- Fluoride has been reported as having both a positive (Tsutusi *et al.* 1984a, 1984b, 1984c; Tong 1984) and negative effect (Skare *et al.* 1985; Williams 1984; Imai *et al.* 1983) upon unscheduled DNA synthesis.
- Fluoride has been reported as having both a positive (Aliev and Babaev 1983; Aliev *et al.* 1982; Mohamed and Chandler 1976 which was criticized by NAS 1977 and Taves 1979; Mohamed and Chandler 1982) and negative effect (Martin *et al.* 1979) upon chromosome

aberrations in the bone marrow of laboratory animals.

EPA cannot conclude that fluoride may present a mutagenic hazard to humans. There are several negative studies and a few positive studies that appear to have been properly conducted; these studies conflict. The reasons why several studies are not deemed significant and a dicussion of the conflicting evidence is presented at greater length in the Comment and Response Document. However, EPA cannot conclude that fluoride may have mutagenic effects on humans.

In reaching a decision, the EPA has balanced the strengths and weakness of each study and all studies together to determine "the weight of the evidence" in the light of the proposed EPA guidelines for mutagenicity (EPA 1984b). These guidelines define a mutagen as a chemical substance or mixture of substances that can induce alterations in the DNA of either somatic or germinal cells. These include point mutations (i.e. changes in the base sequence of DNA) and structural or numerical chromosome aberrations. Structural aberrations include deficiencies, duplications, inversions and translocations. Numerical aberrations include gains or losses of whole chromosomes or sets of chromosomes.

A qualitative determination of the mutagenicity of any compound must consider the extent, quality and consistency of responses bearing on an agent's ability to produce mutagenic events. Because of the variability of responses in the various test systems, limitations in the quality to the studies evaluated and the lack of a clear trend of adequate evidence demonstrating either a positive or negative mutagenic response, an unequivocal determination of the mutagenicity of fluoride cannot be made. In that a number of the studies conflict, it would be desirable if the positive studies were replicated.

4. *Hydrogen Bonding of Fluoride.* A number of comments, quoting the theoretical work of Emsley *et al.* (1980, 1982), concluded that there was evidence that *ionic* fluoride could form strong hydrogen bonds with DNA. It was further postulated that this might disrupt DNA thus leading to a mutagenic or oncogenic response.

EPA Response. While it is possible that the work of Emsley *et al.* (1980, 1982) may offer an explanation as to the biochemistry of fluoride, there are inadequate data to determine what biological significance, if any, should be assigned to these data. In any case, there are more direct data on mutagenicity and oncogenicity and, based on a review of these data EPA concludes that there is an inadequate basis to conclude that fluoride is oncogenic or mutagenic.

5. *Bioavailability of Fluoride.* Several comments concluded that the fluoride normally found in hard water was safe because the calcium and or magnesium found in hard water rendered the fluoride insoluble and thus not available for absorption (decreased bioavailability).

EPA Response. While there is evidence that fluorides administered as a solid (an unlikely event in the case of drinking water) are absorbed less than might be expected (roughly 65% and 37% of the fluoride was absorbed from solid cryolite and bone meal respectively), there is no evidence that the hardness of water will have an appreciable effect upon the bioavailability of fluoride in drinking water (WHO 1970).

6. *Disease, Fluoride Consumption, and Elimination.* A number of comments stated that certain individuals may, due to disease or other unknown factors, markedly (1) increase water intake and thus the amount of fluoride ingested, or (2) decrease the rate of fluoride elimination, leading in both cases to a sensitive population at increased risk of crippling skeletal fluorosis. Specifically:

- A number of comments stated that there are diseases—e.g. diabetes insipidus and mellitus—which result in the consumption of large quantities of water which could result in the ingestion of large quantities of fluoride in high fluoride communities.
- Several comments pointed out that two cases of crippling skeletal fluorosis, possibly due to disease, were associated with the consumption of large quantities of water (Goldman *et al.* 1971; Sauerbrunn *et al.* 1965). (See also *EPA Response: Option 2*, above.)
- Several comments pointed out that much more severe dental (Klein 1975; Greenberg *et al.* 1974) and non-crippling skeletal fluorosis (Juncos and Donadio 1972) than expected have been observed in several individuals who consumed large volumes of water daily.
- Several comments pointed out that the renal clearance of fluoride (a measure of the ability of the kidney to eliminate fluoride) was markedly reduced in some children with kidney disease thus suggesting that more fluoride than normal may be retained in these children (Spak *et al.* 1985).

EPA Response. The Agency agrees that certain segments of the general population may be at increased risk from waterborne fluoride (EPA 1985). For example, polydipsia and polyuria associated with diabetes insipidus and some forms of renal impairment may result in an excessive intake of drinking water and waterborne fluoride. The renal clearance of fluoride (a measure of the kidneys ability to excrete fluoride) may be markedly reduced in some patients with kidney disease, thus suggesting that more fluoride than normal may be retained in these patients (Spak *et al.*, 1985, Schiffl and Binswanger 1980).

The findings of several investigators suggest that individuals with renal impairment and drinking disorders (e.g., polydipsia) are at increased risk of developing both skeletal (not crippling) and/or dental fluorosis (Juncos and Donaido 1972; Largent *et al.* 1951; Hanhijarvi *et al.* 1972; Oreopoulous 1974). Two cases of crippling skeletal fluorosis—associated with the consumption of large quantities of drinking water—have been observed in the U.S. (Goldman *et al.* 1971; Sauerbrunn *et al.* 1965). This does not mean that people with diseases such as diabetes insipidus are at significantly greater risk of developing crippling skeletal fluorosis. Specifically, only two cases of crippling skeletal fluorosis associated with polydipsia have been observed in the U.S. thus suggesting that the incidence is very negligible.

Other data recently submitted to the Agency for review (Greenberg *et al.* 1974; Klein 1975) present case studies of patients with nephrogenic diabetes insipidus and for whom fluoridated water (even at 0.5 ppm) is associated with mild to severe dental fluorosis. However, dental fluorosis is not considered an adverse health effect within the meaning of the Safe Drinking Water Act. No crippling skeletal fluorosis was reported in those studies.

EPA can find no evidence adequate to conclude that fluoride results in allergic or idiosyncratic sensitivity (See 8 below).

No data were identified that supported concerns that individuals with arthritis, thyroid impairment, cancer or that the fetus, the infant, the elderly the sick or malnourished are at risk due to fluoridation of drinking water. The Agency is unware of any other subpopulations which are at particular risk to waterborne fluoride.

In conclusion, the Agency is acutely aware of sensitive subgroups in the population. Under the SDWA, EPA is charged with setting standards to protect the most sensitive subgroup of a population. The RMCL is established at a level at which "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." In this regard, the RMCL was proposed at 4 mg/l to protect against the crippling

effects of skeletal fluorosis (EPA 1985). The Agency feels that this RMCL provides an adequate margin of safety except in those very extreme cases involving severely renally impaired individuals who consume unusually high levels of fluoride due in part to polydipsia and other confounding factors.

7. *Osteosclerosis.* A number of commenters argued, but provided no new data to the Agency, that osteosclerosis is an adverse health effect because osteosclerosis is an early sign of crippling skeletal fluorosis and that the proposed RMCL of 4 mg/L will not protect against osteosclerosis.

EPA Response. As stated in the May 14, 1985 proposal and the Drinking Water Criteria Document on Fluoride (EPA 1985) and in agreement with NAS (NAS 1977; NAS 1980), EPA agrees that chronic ingestion of high levels of fluoride can result in osteosclerosis. However, in agreement with the Surgeon General (Shapiro 1983; Koop 1984), the Agency can find no evidence that fluoride induced increases in bone density, osteosclerosis, result in bodily harm or impaired functioning of the body. No new evidence or argument on this point was received in public comment. Therefore, the EPA reaffirms its conclusion that fluoride induced osteosclerosis is not an adverse health effect within the meaning of the SDWA.

8. *Other Toxic Effects.* A number of comments provided studies, that in some cases were new to the Agency, which concluded or suggested that exposure to fluoride may result in one or more of the following toxic symptoms:

- Sensitivity and or allergic effects (See EPA response, below, for studies)
- Effects on collagen (Uslu (1983)
- Enzyme inhibition (Sulivan and Knobelsdorff 1962; Manocha *et al.* 1975)
- Gilberts Disease—hyperbilirubinemia. (Lee 1982)
- Kidney stones and or damage (Manocha *et al.* 1975; Summers and Kietzer 1975)
- Fluoride crosses the placenta (Feltman and Kosel 1961; Hudson *et al.* 1967)

In addition, while no new information was provided, a number of comments concluded that exposure to fluoride results in one or more of the following toxic effects:

- Teratogenic effects.
- Reproductive effects.
- Thyroid effects.
- Cardiovascular effects.
- Stunting of growth.
- Other effects.

EPA Response. EPA has reached the following conclusions regarding these studies:

In order to establish that exposure to a substance in drinking water results in sensitivity and or allergic effects, certain criteria must be met, including (Goldstein *et al.* 1974):

- A double-blind study in which neither the experimenter nor the patient knows the identity of the substance tested (test compounds or placebo) and thus the potential for experimental bias is minimized.
- Chemical characterization of the substance tested so that any positive response is due to the substance of interest—i.e. flouride—and not due to some unrelated chemical.
- Use of adequate sample size and methods of statistical analysis.
- The study must be relevant to the consumption of drinking water—e.g. both a relevant fluoride concentration and route of exposure should be used.

The case studies reported by Feldman (1983), Petraborg (1974, 1977) and Waldbott (1980) did not employ double-blind techniques and thus the objectivity and conclusions of these studies are questionable. As case reports, these studies do not lend themselves to statistical analysis. Also, since chemical characterization was lacking, a true cause-effect relationship could not be established. The study by Feldman and Kosel (1961) is also inadequate to draw conclusions concerning sensitivity to fluoride. This study was designed to investigate placental transfer of fluoride. However, the authors did not present the details of their findings on fluoride sensitivity. Neither sample size, incidence of adverse effects nor methods of statistical analysis were described.

WHO (1970) has expressed doubt that true sensitivity to fluoride exists: billions of people worldwide are regularly exposed to fluoride through tea drinking yet no subpopulation that is sensitive to fluoride has been identified. In addition, there should have been more reports of adverse effects in the studies in which fluoride tablets were given to school children (at least 10,000 children by 1967, mainly in Switzerland) (O'Meara 1968). While methoxyflurane anesthesia typically increases serum fluoride levels by 30–50 times normal (Fry *et al.* 1973), no cases of fluoride intolerance have been identified in the 12 million patients estimated to have received methoxyflurane (NAS–NRC, 1971).

Thus, in agreement with WHO (1970) and NAS (1977), the EPA finds that there is inadequate evidence to conclude that exposure to fluoride in drinking water results in sensitivity and/or allergic effects.

- The available data are indequate to conclude that exposure to fluoride in drinking water results in adverse effects (Uslu 1983).
- While a number of enzymes are inhibited by fluoride under *in vitro* conditions, there is no convincing evidence (Sullivan and Knobelsdorff 1962; Manocha *et al.* 1975) that significant enzyme inhibition associated with fluoride in U.S. drinking water occurs in humans; however, even if such were the case, there is no evidence to suggest that such inhibition leads to some adverse health effect not previously identified —i.e. crippling skeletal fluorosis.
- The conclusion that fluoride crosses the placenta or in to be found in the placenta (Feltman and Kosel 1961; Hudson *et al.* 1967), or any other tissue, is irrelevant, because no adverse health effect is related to this presence of fluoride. There is no evidence that exposure to fluoride in U.S. drinking water is associated with injury to the mother, fetus or placenta.
- Lee (1982) has suggested that Gilberts Disease, "a benign constitutional liver disorder", may be associated with exposure to relatively low levels of fluoride (0.9–1.2 mg/L) in drinking water. However, Lee (1982) stated that these data are "of heuristic value" and further work is needed before a determination can be made that flouride in drinking water is or is not associated with Gilberts Disease—hyperbilirubinemia (Lee 1982). EPA agrees that additional research is needed in this area before these associations can be concluded.
- While high levels of fluoride—100 mg/L—can result in kidney damage (Hodge and Smith 1965, as discussed in EPA 1985), there are no human or experimental animal data adequate to conclude that exposure to fluoride in U.S. drinking water leads to renal toxicity. In addition, there are inadequate data to conclude that exposure to fluoride in U.S. drinking water (Summers and Keitzer 1975) lead to the development of kidney stones.

Based on the Drinking Water Criteria Document on Fluoride (EPA 1985), the public comments and the EPA response to those comments, the EPA has determined that there is inadequate evidence to conclude that exposure to fluoride in U.S. drinking water is associated with any of the following toxic effects:

- Teratogenic effects,
- Reproductive effects,
- Thyroid effects,
- Cardiovascular effects, and
- Stunting of growth.

9. *Fluoridation.* A large number of comments objected to the fluoridation of drinking water.

EPA Response. Fluoridation is not within the scope of the May 14, 1985 proposal nor is it within the purview of the SDWA. In response to the comments, EPA notes that fluoridation is a matter of State and local authorities. The SDWA prohibits EPA from requiring the addition of any substance for preventative health care purposes unrelated to contamination of drinking water (including fluoride). SWDA Section 1412(b)(6).

Because the RMCL is set at 4 mg/L and fluoridation is practiced at levels of 0.7–1.4 mg/L, fluoridation is not expected to be affected by this regulation. EPA is not, by this final regulation, endorsing fluoridation or fluoridation at a higher level. However, there is no evidence adequate to conclude that water fluoridated at 0.7–1.4 mg/L presents any health hazard.

The NIPDWR include the following statement, "Fluoride at optimum levels has been shown to have beneficial effects in reducing the occurrence of tooth decay." The purpose of including this statement in the regulation was to clarify any perceived conflicts between the beneficial effects at fluoride and potential adverse health effects of higher levels.

10. *Response to South Carolina Petition.* Many commenters stated that the allowable fluoride levels should not be raised to minimize possible high costs of controlling fluoride in such states as South Carolina where fluoride is naturally high. These persons believed that the RMCL was being raised to grant economic relief in response to South Carolina's petition and lawsuit and was not properly based on health concerns.

EPA Response. The RMCL is based only on health considerations and is not being raised to grant economic relief. While the South Carolina petition requested that the fluoride regulations be deleted as a NPDWR, the subsequent lawsuit only set a schedule for these proposals and final rules. EPA did not agree to raise the level in response to South Carolina's actions; this regulation is based on the Agency's evaluation of adverse health effects and the levels necessary to protect against them.

VI. Effective Date

The final RMCL is effective December 16, 1985. As explained above, an RMCL is only a health goal used by EPA; public water systems are not required to meet the RMCL. States are not required to adopt the RMCL to retain primacy.

VII. Public Docket References

All supporting material pertinent to the development of this final rule are included in the public docket located at EPA headquarters, Washington, DC. The two public dockets (i.e., RMCL rulemaking docket-closed and the MCL docket) are available to the public and the public should contact the Drinking Water Regulations Docket Manager for access.

Materials in the public docket include such documents as the following:

- Public comments on the May 14, 1985 Proposed Rulemaking for fluoride.
- Summary of comments and responses.
- Transcript of the June 17–18, 1985 public meeting.
- Transcripts of NDWAC meetings.
- Summaries of meetings, telephone calls from outside EPA.
- Letters to/from the public.
- Fluoride Health Effects Criteria and Occurrence Documents (EPA 1985).
- Summary of Comments and Responses from the May 14, 1985, Fluoride RMCL Proposal.
- Technical reports.
- Other supporting materials.

The following supporting documentation for this proposal is available for inspection at the address listed in the MCL proposal for fluoride published in a separate **Federal Register** document today.

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VIII. Regulatory Analyses

The proposal of an RMCL is different than the proposal of an MCL in that an RMCL is, by law, to be based only on health and safety considerations while an MCL takes feasibility and cost into consideration. Therefore, this RMCL proposal notice does not include an analysis of the economic impact of various possible MCLs. However, the Agency has analyzed the probable impact of the various alternatives, and this is reported in the MCL proposal.

The economic impact assessment includes an analysis of the impact of the various alternatives on the water supply industry vis-a-vis capital costs of technology, operating and maintenance costs and the feasibility of financing new treatments. Additionally, impact on the consumer and on the nation as a whole is presented.

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirements of a Regulatory Impact Analysis. This action does not constitute a "major" regulatory action because it will not have a major financial or adverse impact on the community and it is a non-enforceable regulation. This regulation was submitted to OMB under Executive Order 12291.

Under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, I certify that this action will not have a significant impact on a substantial number of small entities. This action will have no economic impact in and of itself because this is a non-enforceable health goal.

This rule contains no information collection requirements under the provision of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

List of Subjects in 40 CFR Part 141

Chemicals, Intergovernmental relations, Fluoride, Reporting and record keeping requirements, Water supply.

Dated: October 30, 1985.

Lee M. Thomas,

Administrator.

For the reasons set out in the preamble, Part 141 of Title 40, Code of Federal Regulations is amended as set forth below.

PART 141—NATIONAL INTERIM PRIMARY DRINKING WATER REGULATIONS

1. The authority citation for Part 141 continues to read as follows:

Authority: 42 U.S.C. 300g–1, 300g–3, 300j–4, and 300j–9.

2. Section 141.51 is added to read as follows:

§ 141.51 Recommended Maximum contaminant levels for inorganic contaminants.

(a) [Reserved]

(b) RMCLs for the following contaminants are as indicated:

Contaminant	RMCL in mg/L
(1) Fluoride	4.0
(2) [Reserved]	

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